

**K102642 SONOSCAPE ULTRASOUND SYSTEM AND  
TRANSDUCERS MODEL SSI-8000, 2P1 PHASED ARRAY, 5P1  
PHASED ARRAY MODEL 2P1, 5P1, 6V1 MICRO**Mar 4, 2011  
172 days to decisionK102642 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k102642/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Sep 13, 2010                                      |
| Decision date         | Mar 4, 2011                                       |
| Days to decision      | 172 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Sonoscape Company Limited</b>        |
| Location       | Dublin, CA, US                          |
| Contact        | MIN YAO                                 |
| 510(k) history | 22 submissions · 22 cleared · 2004-2015 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102642/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026